CLAIMS

We Claim:

1. A process for producing ribavirin pellets, comprising the steps of:

   mixing ribavirin with at least one excipient into a uniform mixture;

   forming said uniform mixture into a granulated mass by adding a wetting agent to said uniform mixture;

   shaping said granulated mass into flowable particles; and drying said flowable particles.

2. A process according to Claim 1, wherein said excipient is povidone, starch, lactose, polyethylene glycol, and hydroxy propylmethyl cellulose.

3. A process according to Claim 1, wherein said excipient is selected from a group consisting of croscarmellose sodium, starch, cellulose, bentonite, and cross-povidones.

4. A process according to Claim 1, wherein said wetting agent consists of purified water USP.

5. A process according to Claim 1, wherein a filler is added to the ribavirin.

6. A process according to Claim 5, wherein said filler is selected from a group consisting of microcrystalline cellulose, lactose, sucrose, cellulose and starch.

7. A process according to Claim 5, wherein said step of mixing is accomplished by adding said filler in accordance with said uniform mixture, resulting in said uniform mixture consisting of ingredients containing between 40% and 50% filler by weight.

8. A process according to Claim 1, wherein said step of mixing is accomplished by adding excipient, resulting in said uniform mixture consisting of ingredients containing from 1% to 9% excipient by weight.

9. A process according to Claim 1, wherein said step of mixing is accomplished by adding said ribavirin, resulting in said uniform mixture consisting of ingredients

containing between 35% to 80% ribavirin by weight.

10. A process according to Claim 1, wherein achievement of a granulated mass is accomplished by said step of mixing until a smooth granulated mass is formed.

11. A process according to Claim 1, wherein said step of shaping is accomplished by a further step of spheronizing said granulated mass until uniform sized pellets are produced.

12. A process according to Claim 11, wherein said step of shaping is accomplished by said step of spheronizing said granulated mass until said uniform sized pellets are produced and by a further step of extruding said uniform sized pellets through a screen whereby said screen ranges in size from a 0.40 mm screen to a 1.0 mm screen.

13. A process according to Claim 1, wherein said step of drying is accomplished through a further step of heating said mixture to a temperature ranging from 35° Celsius to 45° Celsius, until said mixture contains a moisture content ranging from 0.5% to 5.0%.

14. A process according to Claim 1, wherein a capsule is filled with said dried flowable particles.

15. A process for producing ribavirin pharmaceutical pellets, comprising the steps of:

mixing said ribavirin USP with a filler, a disintegrant and a lubricant resulting in a mixture containing a range from 40% to 50% of said filler by weight, a range from 1% to 9% of said disintegrant by weight and a range from 35% to 80% of said ribavirin by weight;

adding sufficient wetting agent to said mixture, resulting in the formation of an extrudable mass;

shaping said extrudable mass into pellets; and

drying said pellets.

16. A process according to Claim 15, wherein said filler is selected from the group consisting of microcrystalline cellulose, lactose, sucrose, cellulose and starch.

17. A process according to Claim 15, wherein said disintegrant is a selected from a group consisting of croscarmellose sodium, starch, cellulose and bentonite.

18. A process according to Claim 15, wherein said step of shaping is accomplished by a further step of spheronizing said extruded mass until a uniform size of said pellets is produced.

19. A process according to Claim 15, wherein said step of shaping is accomplished by a further step of spheronizing said extrudable mass until a uniform size of pellets is produced and a further step of extruding said pellets through a screen, whereby said screen ranges in size from a .40 mm screen to a 1.0 mm screen.

20. A process according to Claim 15, wherein said step of drying is accomplished by a further step of heating said mixture to a temperature ranging from 35° Celsius to 45° Celsius until said mixture produces a moisture content ranging from 0.5% and 5.0%.

21. A process according to Claim 15, wherein a size "1" capsule is completely filled with said dried pellets such that the filled capsule is produced containing a range of 180 mg to 220 mg of said ribavirin, resulting in said size 1 capsule and having a total weight ranging from 243 mg to 297 mg.

22. A process according to Claim 15, wherein a size "1el" capsule is completely filled with said dried pellets such that the filled capsule is produced containing a range of 180 mg to 220 mg of said ribavirin, resulting in said size 1el capsule and having a total weight ranging from 243 mg to 297 mg.

23. A process according to Claim 15, wherein a size "0" capsule is completely filled with said dried pellets such that the filled capsule is produced containing a range of 270 mg to 330 mg of said ribavirin, resulting in said size 0 capsule and having a total

weight ranging from 364 mg to 446 mg.

24. A process according to Claim 15, wherein a size "00" capsule is completely filled with said dried pellets such that the filled capsule is produced containing a range of 360 mg to 440 mg of said ribavirin, resulting in said size 00 capsule and having a total weight ranging from 486 mg to 594 mg.

25. A process for producing ribavirin pharmaceutical pellets comprising the steps of:

mixing said ribavirin pharmaceutical pellets with microcrystalline cellulose, resulting in said ribavirin and said microcrystalline cellulose forming a mixture containing a range of from 40% to 50% of said microcyrstalline cellulose by weight and a range of from 35% to 80% of said ribavirin by weight;

adding sufficient croscarmellose sodium to said mixture such that the mixed ingredients contain a range from 1% to 9% croscarmellose sodium by weight;

forming said mixed ingredients into an extrudable mass by adding water;

shaping said extrudable mass into pellets;

drying said pellets to produce dried pellets; and

filling capsules with said dried pellets.

26. A process according to Claim 25, wherein said step of shaping is accomplished by a further step of spherionizing said extrudable mass, resulting in a production of uniform sized pellets.

27. A process of Claim 26, wherein said step of shaping is accomplished by a further step of extruding said pellets through a screen ranging from a 0.40 mm screen to a 1.0 mm screen.

28. A process according to Claim 25, wherein said screen is sized between 0.4 mm and 1.0 mm.

29. A process according to Claim 25, wherein said step of drying is accomplished through heating of said mixed ingredients to a temperature ranging from 35° Celsius

to 45° Celsius until said mixed ingredients contain a moisture content ranging from 0.5% to 5.0 %.

30. A process according to Claim 25, wherein a size "1" of said capsules is completely filled, resulting in said pellets containing a total weight ranging from 243 mg to 297 mg.

31. A process according to Claim 25, wherein a size "1el" of said capsules is completely filled, resulting in said pellets containing a total weight ranging from 243 mg to 297 mg.

32. A process according to Claim 25, wherein a size "0" of said capsules is completely filled, resulting in said pellets containing a total weight ranging from 364 mg to 446 mg.

33. A process according to Claim 25, wherein a size "00" of said capsules is completely filled, resulting in said pellets containing a total weight ranging from 486 mg to 594 mg.

34. A process according to Claim 1, wherein at least 90% of said ribavirin dissolves in 30 minutes.

35. A process according to Claim 15, wherein at least 90% of said ribavirin dissolves in 30 minutes.

36. A process according to Claim 1, wherein a coating is added to said dried pellets on an outside surface before encapsulation, resulting in a decreased rate of release during a given time span in comparison to said release under a condition without said coating.

37. A process according to Claim 15, wherein a coating is added to said dried pellets on an outside surface before encapsulation, resulting in a decreased rate of release during a given time span in comparison to said release under a condition without said coating.

38. A process according to Claim 25, wherein a coating is added to said dried pellets on an outside surface before encapsulation, resulting in a decreased rate of release during a given time span in comparison to said release under a condition without said coating.